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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,456	06/18/2001	Michael Houghton	223002010005	1937

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10/02/2009

EXAMINER
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MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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10/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/884,456	<b>Applicant(s)</b> HOUGHTON ET AL.	
	<b>Examiner</b> WILLIAM W. MOORE	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27, 32, 37 and 42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27, 32, 37 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20090904</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4 September 2009 has been entered, canceling claims 28-31, 33-36, 38-41, 43 and 44, and amending claims 27, 32, 37, and 42 to describe, in claims 27 and 32 compositions comprising either the nucleic acid sequence set forth in SEQ ID NO:69 or the nucleic acid sequence set forth in SEQ ID NO:85 and, in claims 37 and 42, expression vectors comprising either the nucleic acid sequence set forth in SEQ ID NO:69 or the nucleic acid sequence set forth in SEQ ID NO:85.

The claim amendments and cancellations remove the bases for (i) the rejections of record of claims herein under the first paragraph of 35 U.S.C. § 112 for lack of enablement and lack of adequate written description, and (ii) the rejections of record of claims herein under 35 U.S.C. § 112, second paragraph and these rejections are, accordingly, WITHDRAWN. The application 10/438,313 is no longer pending and the rejection of record of claims herein over the claims of that application based on nonstatutory double patenting rejection claims is MOOT.

### ***Information Disclosure Statement***

Applicant's Information Disclosure Statement [IDS] filed with the request for continued examination filed on 4 September 2009 is hereby acknowledged. Executed copies of the seventy-four pages of PTO Forms-1449 citing documents that, in most instances, cite documents cited and supplied in the prosecution of application 10/438,313, accompany this communication. Those citations that are duplicative of citations made elsewhere in the IDS, or made in the PTO-Form 892 mailed with the communications of 9 July 2004 and 12 April 2005 are lined-through to prevent duplication in the publication of any patent that may issue on the instant application.

### ***Double Patenting: Non-Statutory***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27, 32, 37, and 42 remain rejected for reasons of record under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 8-11 of U.S. Patent No. 5,371,017. Applicant's arguments at page 4 of the Remarks filed 4 September 2009 have been fully considered but they are not persuasive. Applicant suggests that no terminal disclaimer is necessary because the patented claims "do not recite specific nucleotide sequences" and because the particular nucleic acid sequences required by claims 27, 32, 37, and 42 as amended in the Response filed 4 September 2009 "are not obvious over the claims in the issued patent[ ]" wherein nucleic acid sequences are claimed generically, by their capacity to encode either the 686-amino acid HCV NS3 domain, see the patented claim 2, where Figure 1 to which the claim refers depicts the same 686-amino acid sequence set forth in the patent's SEQ ID NO:70, or the 841-amino acid sequence of a fusion polypeptide comprising the 686-amino acid HCV NS3 domain covalently bound at its amino terminus to the carboxyl-terminus of a human superoxide dismutase [hSOD] 155-amino acid sequence, see the patented claims 8-11 where claim 8 indicates that an expression vector comprises a "polynucleotide encoding HCV protease" the same term used in claim 2 with reference to Figure 1, which is the sequence of SEQ ID NO:70, and claims 9-11 indicate that the vector further comprises an hSOD fusion polypeptide comprising the "HCV protease".

While the patent claim 2 is drawn to a generic polynucleotide encoding the entire 686-amino acid protein of Figure 1, the patent specification discloses only a single polynucleotide species that encodes the 686-amino acid protein: the nucleic acid sequence of SEQ ID NO:69. It would be obvious to the skilled artisan to select this single disclosed nucleic acid sequence species to prepare the nucleic acid sequences and vectors of the patent claims 2 and 8-11 because it is the only species disclosed in the patent specification to encode the 686-amino acid sequence of SEQ ID NO:70 and Figure 1. It would also be obvious to the skilled artisan to select the species of hSOD-HCV fusion protein-encoding that is disclosed in SEQ ID NO:85 of the patent to encode the 841-amino acid sequence of an hSOD-HCV NS3-domain because this is the only fusion polypeptide-encoding nucleic acid sequence particularly taught by the patent specification with which to prepare a fusion polypeptide-encoding nucleic acid sequence to be used in preparing a vector of claims 8-11. There are no other nucleic acid sequence species in the patent disclosure from which one of ordinary skill in the art at the time the invention was

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made might choose as alternative embodiments among a genus encompassed by the patent claims 2 and 8-11, i.e., no other species of different, particular, nucleic acid sequences that might provide different options other than selection of the species of nucleic sequences of SEQ IDs NOs:69 and 85. Where the nucleic acid sequences of SEQ IDs NOs:69 and 85 are the only species on which genera of nucleic acid sequences encoding (1) the protein of the patent claim 2, and present in the vector of the patent claim 8, and (2) the only fusion protein that is disclosed for patent claims 9-11 and present in the vector of the patent claim 8, the subject matters of claims 27, 32, 37, and 42 herein are obvious to the artisan in view of the teachings of the patent specification. The rejection of record herein is therefore maintained until and unless an effective terminal disclaimer is filed.

### ***Conclusion***

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Andrew Wang, can be reached at 571.272.0811. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

/William W. Moore/  
Examiner, Art Unit 1656

/ANAND U DESAI/  
Primary Examiner, Art Unit 1656  
September 30, 2009